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				Application Number	09/760,307-Conf. #8759		
l in	IFORMATION	DISC	LOSURE	Filling Date	January 11, 2001		
S	TATEMENT I	BY AP	PLICANT	First Named Inventor	Sam J. Milstein		
				Art Unit	1615		
	(Use as many sh	eets as nec	essary)	Examiner Name	L. S. Channavajjala		
Sheet	1	of	2	Attamey Docket Number	01946/100A483-US8		

_	U.S. PATENT DOCUMENTS										
Examiner	CNe	Document Number	Publication Date	Name of Patenties or	Pages, Columns, Lines, Where Relevant Passages or Relevant						
my)	'No.1	Number-Kind Code ² (<i>if known</i>)	MM-DD-YYYY	Applicant of Cited Document	Figures Appear						
A .	1	US-6,221,367-B1	04-24-2001	Milstein et al.							
	2	US-6,242,495-B1	06-05-2001	Leone-Bay, et al.							
	3	US-6,245,359-B1	06-12-2001	Milstein, et al.							
	4	US-6,313,088-B1	11-06-2001	Leone-Bay et al.							
	5	US-6,344,213-B1	02-05-2002	Leone-Bay et al.							
	6	US-6,346,242-B1	02-12-2002	Leone-Bay et al.							
	7	US-6,348,207-B1	02-19-2002	Milstein et al.							
	8	US-6,358,504-B1	03-19-2002	Leone-Bay et al.							
	9	US-6,384,278-B1	05-07-2002	Tang, et al.							
	10	US-6,391,303-B1	05-21-2002	Haas et al.							
	11	US-6,399,798-B1	06-04-2002	Gschneider et al.							
	12	US-6,428,780-B1		Leone-Bay et al.							
П	13	US-6,440,929-B1	08-27-2002	Milstein et al.							
	14	US-6,461,643-B1		Milstein et al.							
Π	15	US-6,525,020-B1	02-25-2003	Leone-Bay et al.							
	16	US-2002-0001591-A1	01-03-2002	Santiago et al.							
	17	US-6,610,329-B1	08-26-2003	Santiago et al.							
	18	US-6,623,791-B1	09-23-2003	Leone-Bay et al.							
	19	US-6,642,411-B1		Leone-Bay et al.							
	20	US-6,646,162-B1	11-11-2003	Tang et al.							
	21	US-2002-0120009-A1	08-29-2002	Leone-Bay et al.							
	22	US-6,663,887-B1	12-16-2003	Leone-Bay et al.							
	23	US-6,693,073-B1	02-17-2004	Milstein et al.							
	24	US-6,693,208-B1	02-17-2004	Gschneidner et al.							
	25	US-6,699,467-B1	03-02-2004	Leone-Bay et al.							
W	26	US-6,627,228-B1	09-30-2003	Milstein et al.							

<u> </u>		FORE	GN PATENT	DOCUMENTS		
Examiner	Cite	Foreign Patent Document	Foreign Patent Document Publication Date		Pages, Columns, Lines, Where Relevant Passages	
initials*	No.1	Country Code*-Number*-Kind Code* (# known)	MM-DD-YYYY	Applicant of Cited Document	or Relevant Figures Appear	
	27	WO-01/32130-A1	05-10-2001	Emisphere Technologies, Inc.		
	28	WO-01/32596-A1	05-10-2001	Emisphere Technologies, Inc.		
	29	WO-01/44199-A1	06-21-2001	Emisphere Technologies, Inc.		
\Box	30	WO-01/51454-A1	07-19-2001	Emisphere Technologies, Inc.		
	31	WO-01/70219-A1	09-27-2001	Emisphere Technologies, Inc.		
	32	WO-01/92206-A1	12-06-2001	Emisphere Technologies, Inc.		
	33	WO-02/069937-A1	09-12-2002	Emisphere Technologies, Inc.		
	34	WO-02/070438-A1	09-12-2002	Emisphere Technologies, Inc.		
	35	WO-02/100338-A1	12-19-2002	Emisphere Technologies, Inc.		\Box
	36	WO-02/19969-A1	03-14-2002	Emisphere Technologies, Inc.		\Box
	13/	[V.O.J., 1.1]		permapment retrillonogras, ific.		11
	38	WO-03/045306-A1	06-05-2003	Emisphere Technologies, Inc.		
	39	WO-03/057170-A1	07-17-2003	Emisphere Technologies, Inc.		
	40	WO-03/057650-A1	07-17-2003	Emisphere Technologies, Inc.		
	41	EP-0 576 941-A1	01-05-1994	Nisshin Flour Milling Co., Ltd.		
	42	FR-4446-A1	09-26-1966	Francia Farmaceutica, S.r.l.		

Examiner Signature	annavayele	Date Considered	6	19/	07
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Sut	ostitute for form 1449A/B/I	PTO		Complete if Known			
**				Application Number	09/760,307-Conf. #8759		
11	NFORMATIO	N DISC	LOSURE	Filing Date	January 11, 2001		
S	TATEMENT	BY AP	PLICANT	First Named Inventor	Sam J. Milstein		
	•			Art Unit	1615		
	(Use as many s	iheets as nec	essa/y)	Examiner Name	L. S. Channavajjala		
Sheet	2	of	2	Attorney Docket Number	01946/100A483-US8		

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43	WO-97/47270-A1	12-18-1997 Arad, Dorit	
1 44	WO-99/29705-A1	06-17-1999 Glycomed Inc.	

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Nind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.

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		NON PATENT LITERATURE DOCUMENTS	
xaminer nitials	Cite No.1	and/or country where published	T
K	45	Leone-Bay, A., "N-Acylated alpha-amino acids as novel oral delivery agents for proteins"; Journal of Medicinal Chemistry vol 38, 4263-4269 (1995).	
	46	Leone-Bay, A. "Microsphere Formation in a Series of Derivatized Alpha-Amino Acids: Properties, Molecular Modeling, and Oral Delivery of Salmon Calcitonin"; Journal of Medicinal Chemistry vol 38, 4257-4262 (1995).	
1	47	Ho Koc-Kan, et al. " A Practical Synthesis of -aminoalkanoic acid derivatives form Cycloalkanones" Synthetic Communication, vol. 28, no. 14: 2641-2649 (1996).	
	48	Leone-Bay, A., "4-(4-Salicyloylaminophenyl)butyric Acid as a Novel Oral Delivery Agent for Recombinant Human Growth Hormone" Medi 006, Presented at the American Chemical Society. (March 1996) New Orleans, LA.	
	49	Leone-Bay, A., et al. "The evolution of an oral heparin dosing solution" Drugs of the Future vol 22(8) 885-891 (1997).	
	50	Ho Koc-Kan, et al. " Solution Phase Preparation of Highly Pure Amide Mixtures Via In-Situ Chlorotrimethylsilane Protection and Activation" Synthetic Communication, vol. 27, no. 5: 883-895 (1997).	
	51	Leone-Bay, A. "Acytated non-alpha-amino acids as novel agents for the oral delivery of heparin sodium, USP" Journal of Controlled Release 50: 41-49 (1998).	
	52	Francia Farmaceutica "y-(o-Hydroxybenzamido)-Butyric Acid" Chem Abstracts Vol. 10 114838e (1969).	
	53	Picciola, G., "Sintesi Di Addi Chinazolinonici E Benzossazinonici E Studio Delle Loro Proprieta Antiinfiammatorie" 17, 11 Farmaco, Ed. Sc. vol 31, no. 9 pgs 655-664 (1976).	
	54	Picciola, G., "Synthesis Of Quinazolinone And Benzoxazainone Acids And Study Of Their Anti- Inflammatory Properties" IT, Il Farmaco, Ed. Sc. vol 31, no. 9 pgs 655-664 - English Translation (1976).	
	55	Picciola, G., "Synthesis Of Quinazolinone And Benzoxazainone Acids And Study Of Their Anti- Inflammatory Properties" Chem Abstract 86:5402t (1977).	
	56	Johansen, Marianne, et al. "Pro-Drugs As Drug Delivery Systems XIII. Kinetics Of Decomposition. Of N-Mannich Bases Of Salicylamide And Assessment Of Their Suitability As Possible Prodrugs For Amines" Int. J. Pharm. (1980), 7(2): 119-27 (1980).	
	57	Brown, G. et al., "Receptor Binding Sites Of Hypoglycemic Sulfonylureas And Related!(Acylamino)Alkyl Benzoic Acids" J Med Chem 27, 79-81 (1984).	
	58	Amino Yusuke, et al. * Phenylalanine Derivatives Enhancing Intestinal Absorption of Insulin in Mice * Chem Pharm Bull 36 nos 4426-4434 (1988).	
₩	ָ פני	Prodrugs" Pharmazie 52(4): 272-276 (1997).	ا

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	Application Number		09760307	
	Filing Date		2001-01-11	
INFORMATION DISCLOSURE	First Named Inventor	Sam	J. Milstein	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1615	
(Not for submission under 37 CFR 1.55)	Examiner Name	L. S.	Channavajjala	-
	Attorney Docket Number		01946/100A483-US8	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	•	09760307	
Filing Date		2001-01-11	
First Named Inventor	Sam .	J. Milstein	
Art Unit		1615	
Examiner Name	L. S. (Channavajjala	
Attorney Docket Number		01946/100A483-US8	

A		1	Leone-Bay, et al., "Oral Delivery of Sodium Cromolyn: Preliminary Studies In Vivo and In Vitro", Pharmaceutical Research, Vol. 13, No. 2, pp. 222-226, 1996.							
		Ż	Budavari S. et al., (1996) The Merck Index, 12th Edition page 481							
		3	Budavari S. et al (1996), The Merck Index 12th Edition page 439							
		4	Beer M.U. et al. (1999), Carbohydratye Polymers, 377-380 XP4175852							
		5	European Application No. 98 948 597.4 Office Action dated February 16, 2007							
Ø	6 European Application No. 95 939 863.7 Office Ad		European Application No. 95 939 863.7 Office Action dated February 16, 2007							
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